

# BONUTTI RESEARCH, INC

K964532

FEB -3 1997

## Summary of Safety and Effectiveness *Multitak Suture System*<sup>TM</sup>

- **Submitted by**

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- **Date**

January 29, 1997

- **Trade Name**

*Multitak Suture System*

- **Common Name**

Soft Tissue Anchor

- **Classification Name**

21 CFR 888.3040, Smooth or Threaded Metallic Bone Fixation Fastener

- **Predicate Devices**

- *Multitak SS Suture System*, marketed by Bonutti Research.

- **Device Description**

The anchor is tubular in shape and is preassembled threaded with USP size 2-0 through 2 braided polyester suture. An Introduction Device holds the anchor and delivers it into the bone through a predrilled hole. The sutures can then be used to secure the soft tissue to the bone.

- **Intended Use**

The devices are intended for soft tissue to bone suture fixation for the following indications:

Shoulder

- Rotator cuff tear repairs
- Biceps tenodesis

Foot and Ankle

- Lateral instability repairs/reconstructions

Elbow

- Ulnar or radial collateral ligament reconstructions
- Tennis elbow repair
- Biceps tendon reattachment

Knee

- Extra-capsular repairs:
  - Medial collateral ligament
  - Lateral collateral ligament

- **Performance Data**

Pullout tension testing of the *Multitak* Suture System was performed in cadaver bone and compared to similar testing of the predicate device. Results demonstrated that the performance of the *Multitak* Suture System was equal to or better than the performance of the predicate device.